K091870

SEP 21 2009

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name:	Tornier, Inc.
Contact:	Howard Schrayer Regulatory Affairs Consultant
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Date Prepared June 22, 2009

General Device Information

Product Name: PITON™ Fixation Implant System

Classification: "Non-degradable soft tissue fixation fastener"
Product code: MBI - Class II

Predicate Device

Tornier, Inc.	CINCH™ Fixation Implant System. [510(k) Number K080335]
Smith & Nephew, Inc..	TwinFix Ti 2.8mm, 3.5mm and BioRaptor 2.9mm Suture Anchors [510(k) K053344]

Description

The PITON™ Fixation Implant System includes a 2.8 mm diameter bone anchor and a disposable pre-loaded anchor Inserter. The PITON™ Fixation Implant is designed to secure soft tissue to bone using USP #2 high strength non-absorbable UHMWPE braided suture. The device is designed for inserting the implant directly into bone without a pre-drilled, punched, or tapped pilot hole.

The PITON™ Anchor configuration is comprised of a curved titanium base and a flared nitinol clip.

Intended Use (Indications)

The Tornier PITON™ Fixation Implant is intended for fixation of soft tissue to bone.

The PITON™ Implant is intended for use in the following applications:

- **Shoulder:** Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulabral Reconstruction
- **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament Repair
- **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair. Illiotibial Band Tenodesis
- **Hand/Wrist:** Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
- **Elbow:** Biceps Tendon Reattachment, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
- **Pelvis:** Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency
- **Hip:** Capsular Repair – Acetabular Labral Repair

Substantial Equivalence

This submission supports the position that the Tornier PITON™ Fixation Implant System is substantially equivalent to previously cleared devices, including those listed above. A number of predicate devices list the same range of clinical uses.

Conclusions

Tornier, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the Tornier PITON™ Fixation Implant System. The materials from which the Tornier device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2009

Tornier, Inc.
% Mr. Howard Schrayer
Regulatory Affairs Consultant
100 Cummings Center, Suite 444C
Beverly, Massachusetts 01915

Re: K091870
Trade/Device Name: Tornier, PITON™ Fixation Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: June 22, 2009
Received: June 23, 2009

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Tornier, PITON™ Fixation Implant System

Indications For Use:

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The PITON™ Implant is intended for use in the following applications:
Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulabral Reconstruction
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Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair. Illiotibial Band Tenodesis
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Elbow: Biceps Tendon Reattachment, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction
Pelvis: Bladder Neck Suspension for female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency
Hip: Capsular Repair – Acetabular Labral Repair

Prescription Use ____X_____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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